REMARKS

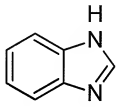
Upon entry of the foregoing listing of claims, claims 1, 34, 36, 37, 39, and 41 have been amended. Claims 1, 29, and 34-41 are currently pending and under consideration. Support for the instant amendment can be found, e.g., at the paragraph bridging pages 102 – 103. No new matter has been added.

Claim Rejections under 35 U.S.C. § 103(a)

The Office Action rejects claims 1, 29, and 34-40 under 35 U.S.C. § 103(a) as allegedly unpatentable over Callahan et al. (U.S. Patent No. 6,492,425; hereinafter CALLAHAN) in view of Sasaki et al., (*Molecular Cancer Therapeutics* **1**:1201-1209, 2002; hereinafter SASAKI),and further in view of Franz et al. (U.S. Patent No. 3,906,034; hereinafter FRANZ). In particular, the Office Action states that CALLAHAN teaches methods of treating cancer comprising compounds wherein a major portion of said compounds is identical to the instant claimed compounds. The Office concedes that CALLAHAN does not teach Applcant's elected compound having two CF3 substituents, or the specific instantly claimed cancers. For these missing features the Office relies on SASAKI, which allegedly teaches that mebendazole (MZ) induced depolymerization of tubulin and inhibition of normal spindle formation in non-small cell lung cancer cells, and FRANZ which allegedly teaches structures overlapping with the compounds of CALLAHAN wherein CF3 may be a substituent.

In response, Applicants respectfully submit that the claimed invention is not unpatentable in view of the cited art. In particular, Applicants submit that CALLAHAN and FRANZ are directed to *benzamide* compounds, not *benzimidazole* compounds as the

Office Action asserts. Applicants submit that benzimidazole compounds, such as that described in SASAKI, have the following structure:



Accordingly, Applicants submit that SASAKI represents non-analogous art, and that one of ordinary skill in the art would not have been motivated to combine the teachings of CALLAHAN and/or FRANZ which are directed to benzamide compounds, with the teachings of SASAKI, which are directed to the benzimidazole compound, mebendazole (MZ).

Applicants also submit that it would *not* have been obvious to combine the teachings of the cited references by manipulating the substituents of the core structure of the compounds of CALLAHAN "in order to improve the anti-cancer effects of benzimidazole carbamate compounds" as the Office asserts (Office Action at paragraph bridging pages 6-7) because SASAKI fails to teach a need for improving the anti-cancer effects of MZ. In contrast to the Office's position, Applicants submit that SASAKI teaches the potential *benefits* of MZ over other known anti-cancer agents. For example, SASAKI teaches that oral administration of MZ showed antitumor activity and reduced lung colonies in experimentally induced lung metastases with no toxicity when compared to paclitaxel-treated mice. (SASAKI at paragraph bridging first and second columns on page 1206; Table 1; and Abstract). Furthermore, SASAKI suggests that MZ – not any variants thereof – may be useful as a microtubule inhibitor for lung cancer chemotherapy

even though it has less effect on mitotic spindle formation and depolymerization of tubulin in tumor cells than nocodazole (SASAKI at page 1208, last paragraph). Indeed, SASAKI teaches that MZ inhibits tumor cell growth by inducing apoptosis in tumor cells while sparing normal cells (SASAKI at page 1202, left column, lines 1-4), whereas strong microtubule inhibitors elicit toxicity even in normal cells (Abstract).

Applicants further submit that because one of ordinary skill in the art would not have been motivated to combine the benzimidazole of SASAKI with the benzamide compounds of FRANZ and/or CALLAHAN, and because SASAKI is non-analogous art as set forth above, the Office may not rely on SASAKI for any teaching with respect to the treatment of Non-Small Cell Lung Cancer (NSCLC). Applicants further submit that FRANZ and CALLAHAN fail to teach NSCLC, or even lung cancer. Accordingly, Applicants submit that any reasoned combination of the documents cited would still fail to teach every limitation of the claims.

Based at least on the foregoing, Applicants submit that the claimed invention is not unpatentable over CALLAHAN in view of FRANZ and further in view of SASAKI. Applicants therefore respectfully request reconsideration of the rejection under 35 U.S.C. § 103(a) and withdrawal of the same.

Nonstatutory Obviousness-Type Double-Patenting

The Office Action provisionally rejects claims 1 and 29 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17, 21, and 24-33 of copending U.S. Patent Application No. 10/564,407.

In response, Applicants respectfully request, in accordance with MPEP 1504.06, that the Examiner allow the present application (the earlier filed application) to proceed to issuance, whereby an obviousness-type double patenting rejection can be made (if appropriate) in the copending application.

The Office Action also provisionally rejects claims 1, 29, and 34-41 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 13-14, 19-23, 25-30, and 55-63 of copending U.S. Patent Application No. 10/433,619 in view of Callahan et al.

In response, Applicants submit that claims 1, 29, and 34-41 are not unpatentable over claims 1, 13-14, 19-23, 25-30, and 55-63 of copending U.S. Patent Application No. 10/433,619 in view of Callahan et al. In particular, Applicants submit that the claimed subject matter is directed to methods for therapeutic treatment of skin cancer, melanoma, lung cancer, liver cancer, breast cancer, pancreatic cancer, acute myeloblastic leukemia, multiple myeloma, Lennert's lymphoma, T-cell leukemia, rhabdomyoma, fibrosarcoma, or neuroblastoma in a mammal. In contrast, Callahan et al. contains only a generic teaching of "cancer, including Hodgkin's disease." Accordingly, Applicants submit that it would not have been obvious for one of ordinary skill in the art to combine the teachings of Callahan with the cited claims of the '619 application in order to yield the invention claimed in the instant application. In other words, the Office has set forth no reason or rationale why one of ordinary skill in the art would have combined the claims of the '619 application with the generic teaching of "cancer, including Hodgkin'sdisease" of Callahan et al. to arrive at Applicants' claimed methods directed to the treatment of skin

cancer, melanoma, lung cancer, liver cancer, breast cancer, pancreatic cancer, acute myeloblastic leukemia, multiple myeloma, Lennert's lymphoma, T-cell leukemia, rhabdomyoma, fibrosarcoma, or neuroblastoma in a mammal.

Based at least on the foregoing, Applicants respectfully request that the Examiner reconsider the provisional rejection of claims 1, 29, and 34-41 on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 1, 13-14, 19-23, 25-30, and 55-63 of copending U.S. Patent Application No. 10/433,619 in view of Callahan et al., and that the Examiner withdrawal the same.

CONCLUSION

For the reasons discussed above, it is respectfully submitted that the rejections be withdrawn. Favorable consideration with early allowance of all of the pending claims is most earnestly requested.

If there are any comments or questions, the undersigned may be contacted at the below-listed telephone number.

Respectfully submitted,
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